Washington State Health Care Authority

Manufacturer Information Submission Form for Affordability Review: [Drug Name]

Washington State Health Care Authority
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[Month Day Year]

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Background Information

Generic Name

[generic name]

Brand Name

[brand name (this "Brand Name" subsection can be omitted if the selected drug is a generic)]

Drug Class

- *If the drug belongs to multiple therapeutic classes, list them all.*
- *Classification based on FDB HIC3 in the context of a Clinical Formulation ID (GCN_SEQNO)*
  - [Class 1]
  - [Class 2]

National Drug Code(s) (NDC)

- *List of applicable NDCs for the PDAB Affordability Review*
- *If there are multiple NDCs, a description of each is requested, including information on dosage, formulation, and package size, and the approximate share of revenue that each NDC represents relative to total revenue from sales of the drug in the United States over the most recent 12-month period.*
  - [NDC 1]: [dosage, formulation, package size, approximate share of revenue]
  - [NDC 2]: [dosage, formulation, package size, approximate share of revenue]

Indications and Approval Date by the Food and Drug Administration (FDA)

- *List FDA-approved indications of the drug and FDA approval date*
- *Also, list indication(s) for which the manufacturer is currently seeking approval*
  - [Indication 1]: [approval date, MM/DD/YYYY]
  - [Indication 2] (Write "under review" if the manufacturer is currently seeking approval.)

Orphan Drug Approval Status

- *List of indications with orphan drug approval status if any*
  - [Orphan Indication 1]: [orphan status approval date, MM/DD/YYYY]
  - [Orphan Indication 2] (Write "under review" if the manufacturer is currently seeking approval.)

Drug Shortage Status

- *Based on the list published by the United States food and drug administration, as well as information available from the manufacturer*

NDC	Formulation	Strength	Estimated Shortage Duration	Related Information	Shortage Reason

Manufacturer Contact Information

- *Provide the name and contact information of an individual who will be able to answer questions regarding the information submitted to the Health Care Authority.*

Contact Information	
Name of Manufacturer	
Contact Name	
Contact Title	
Email Address	
Telephone Number	
Street Address	
City	
State	
Zip	
Washington (WA) Drug Price Transparency (DPT) Number (if applicable)	

Drug Efficacy and Safety

- *This section is intended to give the board and the public general background information on the reviewed drug by succinctly summarizing what outcomes were measured for the drug approval, how well the medication works, and what safety concerns exist.*
- *If the drug has multiple indications with different drug efficacy or safety profiles, information for each indication is requested.*
- *Word limit is 1000 words per indication. Any additional details can be submitted as supplemental information if desired by manufacturers.*
- *Include in-text numbering citations and a list of full reference information, using an AMA format.*
- *Submission of a copy of the full-text manuscripts and reports (i.e. references) to the portal is requested.*

Indication 1: [Indication]

Clinical Efficacy

- *Outcome measures. Brief description of the treated condition and outcome measures are requested.*
- *Drug efficacy descriptions. Data from clinical trials and real-world evidence (RWE) are summarized. Please explicitly list the measured outcomes.*
- *Any interim data, preliminary data analyses, and publications without a full description of methodology to assess the study quality and potential bias are not to be included (e.g. preliminary reports, conference posters). Summary of preliminary data analyses is permissible for an ongoing study as an exception.*

[Response]

Safety Profile

- *Drug safety descriptions are requested. Common adverse drug reactions (ADR with ≥10% frequencies in clinical trials); ADRs observed with statistical significance in clinical trials, any notable signals from RWE, post-market surveillance concerns, as well as any black-box warning, should be summarized.*

[Response]

Indication 2: [Indication]

Clinical Efficacy

[Response]

Safety Profile

[Response]

Summary Table of Efficacy and Safety

Indication	Efficacy	Safety

References:

[References]

Drug Price Information

Wholesale Acquisition Cost (WAC)

- *Data requested up to the previous five years or the five most current price changes, whichever is longer.*
- ***Action:** Submit via the template excel sheet "WAC."*

National Average Drug Acquisition Cost (NADAC)

- *Data requested up to the previous five years.*
- ***Action:** Submit via the template excel sheet "NADAC."*

Average Manufacturer Price (AMP)

- *Data requested up to the previous five years or the five most current price changes, whichever is longer.*
- ***Action:** Submit via the template excel sheet "AMP."*

The Most Current WAC for a Therapy Duration

- *For the drug indicated for acute condition(s), 1) calculated number of drug units and 2) current WAC for a course of treatment are requested.*
- *For the drug indicated for chronic condition(s), 1) calculated number of drug units and 2) current WAC for a year of treatment (i.e. 365 days of therapy) are requested.*
- *If a drug has multiple indications with varying therapy duration, calculation for each indication is requested.*
- *Each indication should be listed on separate rows of the template excel sheet.*
- ***Action:** Submit via the template excel sheet "WAC for Therapy Duration."*
- *Rationale behind the estimates and any assumptions for the calculation should be described, including but not limited to # units per dose, # doses per day, # days per duration (or 365 if chronic), how weight-based or BSA-based dosing was calculated, how loading vs maintenance dose was incorporated. (500-word max).*

[Response]

Discounts

- *Data requested up to the previous five years or the five most current price changes, whichever is longer.*
- *Pricing information for the Federal Supply Schedule (FSS), the Department of Veterans Affairs (VA), the Department of Defense (DOD), U.S. Coast Guard, the Public Health Service (PHS), the 340B ceiling price, and the Medicare maximum fair price. If no discounted pricing available, type "0.00" for the "Discount Amount Per Unit" column of the template.*
- ***Action:** Submit via the template excel sheet "Discounts."*
- *A narrative can be submitted to supplement information in the data table, such as any relevant contract term (e.g. how long the current discount is in effect) (500-word max).*

[Response]

Rebates

- *Data requested up to the previous five years or the five most current price changes, whichever is longer.*
- ***Action:** Submit via the template excel sheet "Rebates."*
- *A narrative is requested to clarify how estimates are made for different NDCs when rebates are offered as a bundle for multiple products) (500-word max).*

[Response]

Other Price Concessions (if applicable)

- *Data requested up to the previous five years or the five most current price changes, whichever is longer.*
- ***Action:** Submit via the template excel sheet "Other Price Concessions."*

Manufacturer Net Price of Drug Purchases After All Discounts, Rebates, and Other Price Concessions

- *Data requested up to the previous five years or the five most current price changes, whichever is longer.*
- *For the "Entity," both discounted entities mentioned on earlier section (e.g. VA, Medicare) and commercial payers are requested.*
- ***Action:** Submit via the template excel sheet "Manufacturer Net Price."*
- *A narrative is requested to describe how the net price was calculated (500-word max).*

[Response]

Drug Price in Other Developed Countries

- *Information on drug pricing in other developed countries*
- *Narrative explaining factors contributing to price differences between the US and other developed countries can be included. This narrative should be summarized succinctly (200-word limit per country) if desired by the manufacturer.*
- *In the narrative, a brief description of how the currency conversion was made is requested (200-word limit for the currency conversion description).*
- *The provided table can be edited to include only countries where the drug is marketed.*

Country	Equivalent NDC in the US	Unit Price (USD)	Price Effective Date (YYYYMMDD)
Australia			
Canada			
France			
Germany			
Italy			
Japan			
Spain			
Sweden			
Switzerland			
United Kingdom			

[Response]

Manufacturing, Delivery, and Administration Cost

Cost of Research and Development (R&D)

- *Narrative and data regarding the R&D costs (i.e. costs incurred for the discovery, clinical trials, and the FDA review and approval process) are requested. 1000-word limit for the narrative (any additional details can be submitted separately as supplemental information if desired by the manufacturer).*
- *No need to include cost information submitted under separate sections (e.g. manufacturing costs etc will be submitted to the separate sections; no need to include this information under the R&D section)*
- *Any external funding sources, grants, and/or tax credits (e.g. any federal and/or state government-related grants, funding from non-profit organizations, public and private foundations), associated with the process of bringing the drug to market including research, discovery, clinical trials, and the FDA review and approval process, should be identified with amounts in a provided table. Indicate whether any FDA priority review voucher was received and, if sold, the revenue generated from the voucher's sale.*
- *If the drug candidate was purchased from another organization or institution during the R&D process, the original funding sources should be identified (e.g. academic funding, federal funding supporting the original developer) as much as possible.*
- *If the drug was purchased from another company, organization, or institution after approval, the purchase amount is requested in a provided table.*
- *A comment on whether the R&D cost was recovered from the drug's market is requested. If the R&D cost has not been recovered yet, estimates on the remaining percentage, as well as the rate of recovery in the future years, are requested. Details on how the numbers are estimated should be included (e.g. any adjustments made for inflation, discounting) (500-word max).*
- *A summary table is requested to illustrate the breakdown of R&D costs, specifying the attributes, dates, and amounts (this table does not count toward the 1000-word limit; the table should be formatted to effectively communicate the breakdown of the R&D costs to the board).*
- *Descriptions of how the costs were estimated or calculated are requested as part of the requested narrative.*

Funding Sources

Source	Year	Value (USD)

Acquisition Cost

Requested Information	Response
Name of entity from which you acquired the drug	
Acquisition date	
Estimated acquisition cost for the drug (USD)	
Description of the methodology used to	

calculate the above estimate for the drug
Acquisition Details (e.g. whether the drug was acquired through the merger with or acquisition of another entity and/or if any other drugs or assets were acquired by your organization from the entity)

Recurring Cost of Drug Manufacturing

- *Recurring drug manufacturing costs for the previous five calendar years. This section asks for information on recurring costs needed to supply the drug (e.g. raw materials, factory labor and overheads). Any costs related to the research and development will be asked under a separate section and should not be included under this section.*
- ***Action:** Submit via the template excel sheet "Manufacturing Recurring Cost."*
- *The breakdown of the manufacturing costs should be included with amounts in the narrative for the most recent year.*
- *Narrative of how variable the production cost has been between years is requested (e.g. manufacturing site transition, new technology adaptation, shortage of raw materials). Any additional insights to supplement the data table would be helpful.*
- *Narrative of what changes are expected in the future if any. Projected future manufacturing costs are requested if any significant change is expected in the manufacturing costs.*
- *The narrative/descriptions are limited to 1000 words. (Any additional details can be submitted separately as supplemental information if desired by the manufacturer.)*

[Response]

Marketing, Advertising, and Lobbying Budget and Expenditures

- *Using the best information available, narratives and data on the marketing budget and expenditure in the aggregate and for the drug are requested (for the narrative, 1000-word max).*
- *In the narrative, include aggregate, company-level prescription drug marketing as a proportion of the manufacturer's total prescription drug expenditures for the last three years for which final audited data are available.*
- *This section should include any budget items and expenditure related to promoting and selling prescription drug products, including market research, advertising, and publicity. It includes, but is not limited to, television, radio, print media, internet advertising and social media, as well as any marketing or promotional activities that are directed to consumers (e.g., contributions to patient advocacy groups) or prescribers (e.g., samples, detailing programs, promotional mailings, dinners, gifts, sponsorship of talks or conferences, branded incidentals), and policymakers (e.g. lobbying).*
- *For the budgets and expenditures targeting consumers and prescribers, both company-level aggregated amounts and drug-specific estimates are requested.*
- ***Action:** Submit via the template excel sheet "Marketing Advertising Lobbying."*
- *Do NOT include amounts for coupons and patient assistance programs. This information is submitted separately in the later sections.*

[Response]

Cost of Delivering the Drug to Patients (if applicable)

- *If patients need to have the drug delivered via a special mechanism from the manufacturer, resulting in any costs to patients, this information is requested.*
- *Yearly averages of the total drug delivery cost for completion of therapy duration during the previous five calendar years are requested.*
- ***Action:** Submit via the template excel sheet "Delivering Cost."*
- *Narrative of what items are included as drug delivery cost is requested.*
- *Narrative of what changes are expected in the future is requested if any.*
- *For the narratives, the word limit is 500 words.*
- *For the drug indicated for chronic condition(s), the cost should be calculated for a 365-day therapy.*
- *For the drug with multiple indications, information is requested for each indication.*
- *Each indication should be listed on separate rows of the template excel sheet.*

[Response]

Cost of Administering the Drug to Patients (if applicable)

- *If patients require any additional supplies to administer the drug, this cost to patients is requested (e.g. syringes, separate solution vials).*
- *Information from the previous five calendar years is requested.*
- ***Action:** Submit via the template excel sheet "Administering Cost."*
- *Narrative of what items are included as administration cost is requested.*
- *Narrative of what changes are expected in the future is requested if any.*
- *For the narratives, the word limit is 500 words.*
- *For the drug indicated for chronic condition(s), the cost should be calculated for a 365-day therapy.*
- *For the drug with multiple indications, information is requested for each indication.*
- *Each indication should be listed on separate rows of the template excel sheet.*

[Response]

Other Administrative Costs (if applicable)

- *Any other costs related to the production and delivery of the drug are requested.*
- *Yearly averages of the other costs for completion of therapy duration during the previous five calendar years*
- ***Action:** Submit via the template excel sheet "Other Admin Costs."*
- *A narrative of what items are included as other administrative costs is requested. A description of how the cost was calculated or estimated is also requested.*
- *A narrative of what changes are expected in the future is requested if applicable.*
- *For the narratives, the word limit is 500 words.*

[Response]

Price Effect on Consumers' Access to the Drug in WA

Prevalence and Incidence of Indicated Condition(s) in the State

- *Prevalence and incidence data of the indicated condition(s) in the State during the previous five calendar years if available. Please include a reference in the AMA style.*
- ***Action:** Submit data via the template excel sheet "Prevalence and Incidence."*
- *If studies providing exact numbers are not available, an estimate is requested for the most recent year. If making an estimate, the description of the method is requested (500-word limit).*

[Response]

Reference:

[Reference]

Estimated Patient's Drug Cost and Utilization in the Nation vs. the State

- *Estimated drug cost to patients between the WA and the national average for the most recent year is requested.*
- ***Action:** Submit via the template excel sheet "Nation vs WA."*
- *The description of the method is requested for making the estimated calculation regarding the patient's out-of-pocket cost to cover the treatment duration. For chronic conditions, estimates should be made for one-year therapy (1000-word limit). If a published reference is available, please include by using the AMA style.*

[Response]

Reference:

[Reference]

Manufacturer Patient Assistance Program and Coupons

Patient Assistance Program (PAP) Availability and Patient Eligibility

- *Information related to the patient assistance program (PAP) is requested. (Any information related to coupons is collected under a later section, so please do not include coupon-related data under this current section.)*
- *500-word limit for the general information.*
- *Information is requested for the previous five calendar years.*
- *For the drug indicated for chronic condition(s), therapy duration is considered 365 days.*
- *For the drug with multiple indications, information is requested for each indication.*
- *Each indication should be listed on separate rows of the template excel sheet.*
- ***Action:** Submit data via the template excel sheet "PAP Eligibility."*

[Response]

PAP-Approved Product Quantity and Dollar Value

- *Information related to the product utilization with the PAP is requested (500-word limit).*
- *Total numbers of drugs requested to and approved by the PAP are requested for the previous five calendar years.*
- *Dollar values equivalent to cover the number of drug units requested to and approved by the PAP are requested for the previous five calendar years.*
- ***Action:** Submit data via the template excel sheet "PAP Qty & Dollar."*

[Response]

Coupon Availability

- *Information related to coupons is requested. (Any information related to the PAP is collected under an earlier section, so please do not include PAP-related data under this current section.)*
- *Information is requested for the previous five calendar years.*
- *For the drug indicated for chronic condition(s), the therapy duration is considered 365 days.*
- *For the drug with multiple indications, information is requested for each indication.*
- *Each indication should be listed on separate rows of the template excel sheet.*
- ***Action:** Submit data via the template excel sheet "Coupon."*

[Response]

Coupon Limitations

- *Description is requested on limitation to use coupons. All limitations existing for use of coupons should be listed, such as any patient ineligibility (those enrolled in Medicare, Medicaid, or other government insurance), the number of refills or days of supply. (500-word limit)*

[Response]

Therapeutically Equivalent Drugs (if applicable)

- *Based on WAC 182-52-0010, "Therapeutic equivalent" means a drug product of the identical base or salt as the specific drug product prescribed with essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.*
- *Availability of generic or biosimilar drugs for a brand drug based on FDA orange or purple book respectively*
- ***Action:** Submit generic drug information via the template excel sheet "Orange Book." (if applicable)*
- ***Action:** Submit biosimilar drug information via the template excel sheet "Purple Book." (if applicable)*

Price and Availability of Therapeutic Alternatives

- *Based on WAC 182-52-0010, "Therapeutic alternative" means a drug product that may contain a different chemical or biological structure than the drug prescribed and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to individuals in a therapeutically equivalent dose.*
- *Inclusion of all drugs considered a therapeutic alternative is requested. All drugs within the same therapeutic class, as well as drugs from different therapeutic classes evaluated within guidelines for treating the same disease and the same severity, should be evaluated under this section.*
- *For the "Guideline recommendations," all guidelines considered current and intended for the US population should be included.*
- *For the "Comparison of Cost," WAC cost should be estimated for a therapy duration, not including any rebates and discounts. For chronic conditions, the cost should be calculated for a 365-day therapy. The cost estimation methodology should be applied to all therapeutic alternatives under this section.*
- *For the "Comparison of Efficacy," descriptions of comparative data are requested based on head-to-head trials if any. If no head-to-head trials exist, data derived from individual clinical studies conducted in a similar patient population are requested. Data from clinical trials and real-world evidence (RWE) can be used. However, any interim data, preliminary data analyses, and publications without a full description of methodology to assess the study quality and potential bias are <u>not</u> to be included (e.g. preliminary reports, conference posters).*
- *For the "Comparison of Safety," create a table listing common side effects from clinical trials and RWE, black-box warning, and any concerning post-market surveillance signals with individual expected rate of occurrences.*
- *Information from domestic and foreign Health Technology Assessment (HTA) organizations and systematic reviews published in peer-reviewed journals, are also requested as part of the following subsection of "Summary Tables of Therapeutic Alternatives" section (i.e. summary table is requested).*
- *The word limit for each therapeutic alternative is 1000 words. Inclusions of tables and/or diagrams are recommended to illustrate the information effectively (and the tables/diagrams do not count toward the word limit).*
- *Include in-text numbering citations and a list of full reference information, using an AMA format.*
- *Submission of a copy of the full-text manuscripts and reports (i.e. references) to the portal is requested.*

Indication 1: [Indication]

Therapeutic Alternative 1

Generic/biosimilar Name: [Response]

Brand Name: [Response]

List of NDCs (11-digit): [Response]

Place in Therapy for Overlapping Indications with the Reviewed Drug: [Response]

Comparison of Guideline Recommendations to Reviewed Drug: [Response]

Comparison of Cost to Reviewed Drug: [Response]

Comparison of Efficacy to Reviewed Drug: [Response]

Comparison of Safety Profile to Reviewed Drug: [Response]

Therapeutic Alternative 2

Generic/biosimilar Name: [Response]

Brand Name: [Response]

List of NDCs (11-digit): [Response]

Place in Therapy for Overlapping Indications with the Reviewed Drug: [Response]

Comparison of Guideline Recommendations to Reviewed Drug: [Response]

Comparison of Cost to Reviewed Drug: [Response]

Comparison of Efficacy to Reviewed Drug: [Response]

Comparison of Safety Profile to Reviewed Drug: [Response]

Summary Tables of Therapeutic Alternatives for Indication 1

Generic/ Biosimilar Name	Brand Name	Place in Therapy	Comparison of Guideline Recommendations To Therapy Drug	Cost Comparison To Reviewed Drug	Efficacy Comparison To Reviewed Drug	Safety Comparison To Reviewed Drug

Institution/ Organization	Clinical Effectiveness Conclusion	Reference Number
Cochrane Library		
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NHCI (Netherlands)		
INAHTA (international)		

References:

[References]

Indication 2: [Indication]

Therapeutic Alternative 3

Generic/biosimilar Name: [Response]

Brand Name: [Response]

List of NDCs (11-digit): [Response]

Place in Therapy for Overlapping Indications with the Reviewed Drug: [Response]

Comparison of Guideline Recommendations to Reviewed Drug: [Response]

Comparison of Cost to Reviewed Drug: [Response]

Comparison of Efficacy to Reviewed Drug: [Response]

Comparison of Safety Profile to Reviewed Drug: [Response]

Therapeutic Alternative 4

Generic/biosimilar Name: [Response]

Brand Name: [Response]

List of NDCs (11-digit): [Response]

Place in Therapy for Overlapping Indications with the Reviewed Drug: [Response]

Comparison of Guideline Recommendations to Reviewed Drug: [Response]

Comparison of Cost to Reviewed Drug: [Response]

Comparison of Efficacy to Reviewed Drug: [Response]

Comparison of Safety Profile to Reviewed Drug: [Response]

Summary Tables of Therapeutic Alternatives for Indication 2

Generic/ Biosimilar Name	Brand Name	Place in Therapy	Comparison of Guideline Recommendations To Therapy Drug	Cost Comparison To Reviewed Drug	Efficacy Comparison To Reviewed Drug	Safety Comparison To Reviewed Drug

Institution/ Organization	Clinical Effectiveness Conclusion	Reference Number
Cochrane Library		
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NHCI (Netherlands)		
INAHTA (international)		

References:

[References]

Same-Class Drug Not Considered Therapeutic Alternative

- *If drugs from the same class are not listed above with the same indication, descriptions of why they are not considered to be therapeutic alternatives are requested.*
- *List of NDCs: character string format. List 11-digit NDCs by separating them with semicolons (;).*

Generic/ Biosimilar Name	Brand Name	List of NDCs (11-digit)	Description Of Why Not Considered Therapeutic Alternative
		11111111111; 22222222222; 33333333333	

Cost-Effectiveness Analysis

- *Based on RCW 70.405.050, the board must not use quality-adjusted life years that take into account a patient's age or severity of illness or disability.*
- *Based in RCW 70.405.050, for the drug that extends life, cost-effectiveness should not employ a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a preexisting disability or chronic health condition.*
- *Summary descriptions of cost-effectiveness analyses are requested. Information from domestic and foreign HTA organizations should be included (e.g. peer-reviewed publications, reports from Cochrane Library, ICER, NICE, CADTH, IQWiG, INAHTA, NCHI)*
- *If the drug has multiple indications, information for each indication is requested.*
- *Include descriptions of study population, comparison groups, and outcomes of interest with the results. Limitations of each study/analysis should also be identified.*
- *Any interim data, preliminary data analyses, and publications without a full description of methodology to assess the study quality and potential bias are not to be included (e.g. preliminary reports, conference posters). Summary of preliminary data analyses is permissible for an ongoing study as an exception.*
- *Include in-text numbering citations and a list of full reference information, using an AMA format.*
- *Submission of a copy of the full-text manuscripts and reports (i.e. references) to the portal is requested.*

Indication 1: [Indication]

Available Cost-Effectiveness Analysis Data: [Response]

Summary Tables:

Study	Study Population	Comparison Groups	Measured Outcomes	Results	Limitations	Reference Number

HTA Organization (Country)	Cost Effectiveness Conclusion	Reference Number
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NHCI (Netherlands)		
INAHTA (international)		

References:

[References]

Indication 2: [Indication]

Available Cost-Effectiveness Analysis Data: [Response]

Summary Tables:

Study	Study Population	Comparison Groups	Measured Outcomes	Results	Limitations	Reference Number

HTA Organization (Country)	Cost Effectiveness Conclusion	Reference Number
ICER (US)		
NICE (UK)		
CADTH (Canada)		
IQWiG (Germany)		
NCHI (Netherlands)		
INAHTA (international)		

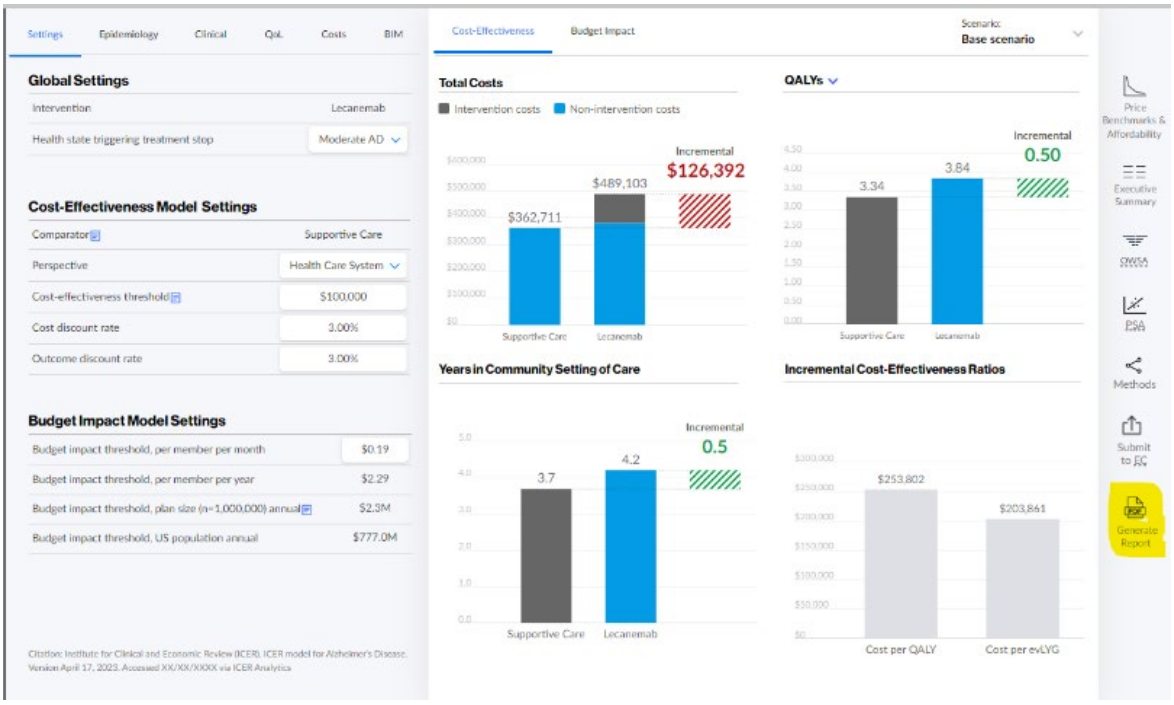
References:

[References]

Interactive Model for the Cost-Effectiveness Analysis

- *Submission of a cost-effectiveness analysis model is strongly recommended by using the ICER Analytics Interactive Modeler, if there is any relevant model published already. In this case, please submit any parameter specifications that need to be adjusted from the base scenario with supporting documents and justifications for the adjustments. Please create a table under this section to compare between ICER original values and updated values with a list of citations. Additionally, use the "Generate Report" option to download your model from the ICER Analytics as a PDF file.*

Parameters Changed	ICER Value	Manufacturer Alternative Value	Source/Citation



- *Alternatively, a copy of the in-house model file for cost-effectiveness analysis in an Excel file can be submitted. A detailed description or a manual explaining the model, the parameters, and assumptions are requested, so that the HCA staff can verify and make adjustments if needed for the Board's requests.*

Additional Information from the Drug Manufacturer

- *If the drug has multiple indications, information for each indication is requested.*
- *Include in-text numbering citations and a list of full reference information, using an AMA format.*
- *Submission of a copy of the full-text manuscripts and reports (i.e. references) to the portal is requested.*

Exclusivity and Patent Expiration Date (if applicable)

- *A concise list of exclusivities and patents are requested with the expiration dates (100-word limit).*

[Response]

Relevant Information on Exclusivity and the Patent Expiration Date (if applicable):

- *Description of an earliest date a generic/biosimilar product can enter the market is requested. If there is any additional information related to the exclusivity and patent expiration, potentially resulting in delays in generics/biosimilars entering the market, relevant information is requested (500-word limit).*

[Response]

Life-Cycle Management

- *Current work related to the reviewed drug is requested (500-word limit). This may include but is not limited to reformulation of the product and ongoing clinical studies for potentially a new indication in the future.*
- *If any specific formulation of the drug is expected to have patent protection longer than others, this information is requested.*

[Response]

Indication 1: [Indication]

Market Competition and Context

- *Market competition and contexts with a description of how the market share is defined are requested (500-word limit).*

[Response]

Uptake and Market Share Table

- *Percentages of market share are requested on the provided table.*

	Current Year	Year 1	Year 2	Year 3	Year 4	Year 5
Eligible WA Population	X	X	X	X	X	X
Reviewed Drug	X%	X%	X%	X%	X%	X%
[Therapeutic Alternative 1]	X%	X%	X%	X%	X%	X%

[Therapeutic Alternative 2]	X%	X%	X%	X%	X%	X%

Past Revenue

- *Revenue information on the current year and the past five years is requested.*

	Year -5	Year -4	Year -3	Year -2	Year -1	Current Year
Reviewed Drug						
[Therapeutic Alternative 1]						
[Therapeutic Alternative 2]						

Projected Revenue

- *Revenue projection for the next five years is requested.*

	Current Year	Year 1	Year 2	Year 3	Year 4	Year 5
Reviewed Drug						

Budget Impact Analysis

Reviewed Drug

- *Complete the template table, including details of the treatment regimen and method of administration.*
- *Specify the sources of information and data used to complete the table, for example the prescribing information or trial data.*

Optimization of population	Provide details of any optimization of the population (compared to the indicated population in the state of Washington), or state if no optimization is proposed.	
	Descriptions	**Source**
Acquisition cost (USD)*		
Method of administration		
Dosage		
Average length of a course of treatment		
Average interval between courses of treatments		
Anticipated number of repeat courses of treatments		
Dose adjustments		
*** When the reviewed drug is recommended in combination with other treatments in the Prescribing Information, the price of each intervention should be presented.**		

Health Condition and Position of the Drug in the Treatment Pathway

- *Present the clinical pathway of care that shows the context of the proposed use of the drug within the pathway. This information should be summarized in a diagram.*
- *Describe established clinical practice for the population eligible for treatment with the reviewed drug.*
- *State the line of treatment the reviewed drug will be used in, for example, 'second-line treatment' or 'second-line and third-line treatment.'*
- *Explain how the new technology may change this existing pathway including any impacts on subsequent treatments.*
- *State the comparator technologies being considered.*
- *Where benefits/savings are achieved, show these per each relevant year.*
- *Provide details of other clinical guidelines which are considered current and targeting the US population.*
- *Describe any issues relating to current clinical practice, including any variations or uncertainty about established practice.*

[Response]

Eligible Population

- *Briefly describe the incidence and prevalence of the condition and life expectancy for people with the condition.*
- *State how many people are eligible for treatment with the drug in the state of Washington and for any subgroups considered. Include data for the next 10 years.*
- *Provide details of any assumptions used and include all steps taken to calculate the eligible population.*

[Response]

Resources Necessary for Use of the Reviewed Drug and Therapeutic Alternatives

- *Description of disease-related expenditure is requested.*
- *Description of inclusive treatment costs (e.g. drug acquisition, diagnostic, administration, monitoring, side effect treatment) is requested. Identify use of resource to the Washington payers associated with the reviewed drug.*
- *State whether any concomitant therapies are required by the Prescribing Information or were administered in the key clinical trials (for example, for managing adverse reactions) with the drug.*
- *State if and to what extent the reviewed drug affects patient monitoring, compared with established clinical practice in the US.*
- *Provide a table that clearly sets out all relevant costs for the drug.*
- *This table should include the costs of administration, monitoring, managing adverse events, and any other costs that should be taken into account when assessing the budget impact of the drug.*
- *Provide information (source data, calculations, basis for assumptions) on the unit costs used.*
- *Provide a table that clearly sets out the relevant costs for the therapeutic alternatives or current standard of care. This should include all costs and the information described for the reviewed drug.*

[Response]

Summary Table of Annual Budget Impact

- *A summary table is requested. The suggested table format can be modified to fit the analyzed elements for the 10-year time horizon.*

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Eligible WA Population for Treatment with Reviewed Drug										
WA Population Expected to Receive Reviewed Drug										
Budget of Treatment Without Reviewed Drug										
Budget of Treatment with Reviewed Drug										
Net Budget Impact										

Uncertainty Analysis

- *Description of uncertainty (uncertainty analysis) is requested.*

- *If conducting one-way sensitivity analysis, inclusion of a tornado diagram is requested.*
- *Include different scenarios if applicable.*
- *Include a sensitivity analysis with 100% adherence to the drug regimen, if the adherence level was set at a lower level for the base analysis in the earlier sections of the budget impact analysis.*

[Response]

Limitations of the Budget Impact Assessment

- *Description of limitations to the current budget impact assessment is requested (500-word limit).*

[Response]

References:

[Reference]

Indication 2: [Indication]

Market Competition and Context

- *Market competition and contexts with a description of how the market share is defined are requested (500-word limit).*

[Response]

Uptake and Market Share Table

- *Percentages of market share are requested on the provided table.*

	Current Year	Year 1	Year 2	Year 3	Year 4	Year 5
Eligible WA Population	X	X	X	X	X	X
Reviewed Drug	X%	X%	X%	X%	X%	X%
[Therapeutic Alternative 1]	X%	X%	X%	X%	X%	X%
[Therapeutic Alternative 2]	X%	X%	X%	X%	X%	X%

Past Revenue

- *Revenue information on the current year and the past five years is requested.*

	Year -5	Year -4	Year -3	Year -2	Year -1	Current Year
Reviewed Drug						
[Therapeutic Alternative 1]						

[Therapeutic Alternative 2]						

Projected Revenue

- *Revenue projection for the next five years is requested.*

	Current Year	Year 1	Year 2	Year 3	Year 4	Year 5
Reviewed Drug						

Budget Impact Analysis

Reviewed Drug

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	Descriptions	**Source**
Acquisition cost (USD)*		
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Dosage		
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- *Where benefits/savings are achieved, show these per each relevant year.*
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[Response]

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[Response]

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[Response]

Summary Table of Annual Budget Impact

- *A summary table is requested. The suggested table format can be modified to fit the analyzed elements for the 10-year time horizon.*

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WA Population Expected to										

Receive Reviewed Drug										
Budget of Treatment Without Reviewed Drug										
Budget of Treatment with Reviewed Drug										
Net Budget Impact										

Uncertainty Analysis

- *Description of uncertainty (uncertainty analysis) is requested.*
- *If conducting one-way sensitivity analysis, inclusion of a tornado diagram is requested.*
- *Include different scenarios if applicable.*
- *Include a sensitivity analysis with 100% adherence to the drug regimen, if the adherence level was set at a lower level for the base analysis in the earlier sections of the budget impact analysis.*

[Response]

Limitations of the Budget Impact Assessment

- *Description of limitations to the current budget impact assessment is requested (500-word limit).*

[Response]

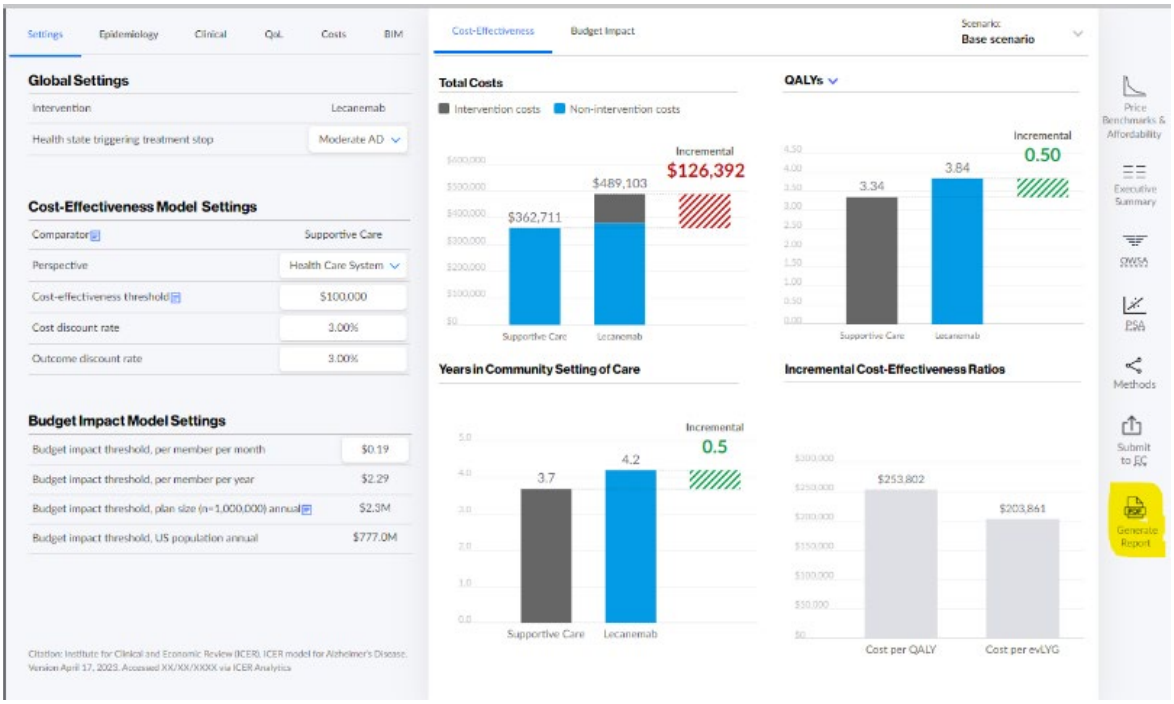
References:

[Reference]

Interactive Model for the Budget Impact Analysis

- ***Action:** Submission of a budget-impact analysis model is strongly recommended by using the ICER Analytics Interactive Modeler, if there is any relevant model published already. In this case, please submit any parameter specifications that need to be adjusted from the base scenario with supporting documents and justifications for the adjustments. Please create a table under this section to compare between ICER original values and updated values with a list of citations. Additionally, use the "Generate Report" option to download your model from the ICER Analytics as a PDF file.*

Parameters Changed	ICER Value	Manufacturer Alternative Value	Source/Citation



- ***Action:*** *Alternatively, a copy of the in-house model file for the budget impact analysis in an Excel format can be submitted. A detailed description or a manual explaining the model, the parameters, and assumptions are requested, so that the HCA staff can verify and make adjustments if needed for the Board's requests.*

Additional Information for Drug Pricing

- *As separately submitted files, provide existing information produced for and reviewed by your organization's senior leadership (e.g., current or previous officers, directors, trustees, partners, senior managers, etc.) sufficient to describe the pricing strategy for the drug, such as memos, PowerPoint presentations, or other communication.*
- *Information relied upon by your organization, including those performed by an independent third-party should be included.*

Off-Label Usage of the Drug (if applicable)

- *List of off-label indications. Information for each off-label indication is requested.*
- *Any drug utilization information for the off-label indications in the state (if available)*
- *Descriptions are requested regarding how estimates are made for the information on the table (500-word max).*

Summary Table for Off-Label Usage

Off-Label Indication	Efficacy Information	Safety Concerns	Estimated Number of Washingtonians Using Drug For Off-Label Indication	Relative Frequency of Use for Off-Label Indication vs. Labeled Indication

[Response]